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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Applicant:	CHANG, Chin-Ming	Group Art Unit: 1654
Serial No.:	10/055509	Examiner: A. Gupta
Application Date:	January 23, 2002	Conf No.: 9159
For:	STABILIZED TERIPARATIDE SOLUTIONS	
Docket No.:	X10911A	

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Introductory Comments

This amendment is submitted under 37 C.F.R. 1.114 as a Request for Continued Examination of the above-captioned application, together with a Petition to Withdraw From Issue the above-captioned application, under 37 C.F.R. 1.313. Applicants respectfully request continued examination of the amended claim set.

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5.

Amendments to the Claims

This listing of claims will replace all prior versions, and listings of claims in the application.

Claims 1-35 (canceled)

36. (previously presented) An aqueous pharmaceutical solution, which comprises: human parathyroid hormone (1-34) in a concentration of about 100-500 ug/ml; an acetate buffer to maintain the pH range of the solution from greater than 3 to 6; a stabilizing agent selected from the group consisting of glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol, glycerine, propylene glycol, and mixtures thereof; a parenterally acceptable preservative; and water; wherein said solution is sterile and ready for parenteral administration to a human patient.

37. (previously presented) The pharmaceutical solution of claim 36 wherein the preservative is selected from m-cresol or benzyl alcohol.

38. (previously presented) The pharmaceutical solution of claim 37 wherein the preservative is m-cresol at a concentration range of about 0.3 to about 1.0% by weight of the solution.

39. (previously presented) The pharmaceutical solution of claim 36, 37, or 38, wherein the stabilizing agent is mannitol at a concentration of about 3% to 10% by weight of the total solution.

40. (previously presented) The pharmaceutical solution of claim 36, 37, or 38 wherein the concentration of the buffer is in the range of about 2mM to 100mM.

41. (previously presented) The pharmaceutical solution of claim 40 wherein the buffer includes acetic acid and sodium acetate.

42. (previously presented) The pharmaceutical solution of claim 36, 37, 38, or 39, wherein said parathyroid hormone concentration is 250 ug/ml.

43. (previously presented) An aqueous pharmaceutical solution, which comprises: 0.25 mg human parathyroid hormone (1-34), 50 mg mannitol, 2.5 mg m-cresol, 0.52 mg acetic acid and 0.12 mg sodium acetate mixed per 1 ml of water, wherein the solution is sterile and ready for parenteral administration to a human patient.

44. (previously presented) A method for preparing a sterile, ready to administer pharmaceutical solution for parenteral administration comprising human parathyroid hormone (1-34), said method comprising the steps of:

a) admixing human parathyroid hormone (1-34) with: an acetate buffer to maintain a pH range from greater than 3 to less than 7; a stabilizing agent selected from the group consisting of glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol, glycerine, propylene glycol, and mixtures thereof; a parenterally acceptable preservative; and water wherein said parathyroid hormone is at a concentration of about 100-500 ug/ml; and

b) sterilizing the solution for parenteral administration without undergoing a step of freeze-drying or reconstitution prior to use by a patient.

45. (previously presented) The method of claim 44, wherein the preservative is m-cresol in a range of about 0.3 to about 1.0% by weight of the solution; the stabilizing agent is about 3 to 10% by weight of the total solution; and the concentration of the buffer system is in the range of about 2mM to 100mM.

46. (previously presented) The method of claim 45, wherein about 0.25 mg human parathyroid hormone (1-34), 50 mg mannitol, 2.5 mg m-cresol, 0.52 mg acetic acid and 0.12 mg sodium acetate are mixed per 1 ml of water.

47. (currently amended) A sealed vial comprising: a sterile, aqueous pharmaceutical solution ready for parenteral administration to a patient, said solution comprising human parathyroid hormone (1-34) in a concentration range from 100 ug/ml to 500 ug/ml; an acetate

or tartrate buffer system to maintain the pH range of the solution from 3 to 6; a stabilizing agent selected from glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol, glycerin, ~~glycine~~ and propylene glycol, or mixtures thereof; a parenterally acceptable preservative; and water; wherein said solution has not been reconstituted in the vial from a powder.

48. (previously presented) The sealed vial of claim 47 wherein the stabilizer is mannitol.

49. (previously presented) The sealed vial of claim 48 wherein the parathyroid hormone (1-34) is at a concentration of 250 ug/ml, the mannitol is at a concentration of about 1% to about 20% by weight of the solution, and the preservative is at a concentration of about 0.1% to about 2% by weight of the solution.

50. (previously presented) A sealed vial as in claim 49 wherein said preservative is selected from m-cresol or benzyl alcohol and the mannitol is at a concentration of about 3 to 10% by weight of the solution.

Remarks

This Request for Continued Examination is made under 37 C.F.R. 1.114 in conjunction with a Petition to withdraw the above-captioned application from issue, after payment of the issue fee. Reconsideration of the application and amendment to the claims is requested.

Claim 47 has been amended to remove glycine from the list of stabilizing agents. Applicants assert no new matter has been added thereby. Applicants respectfully submit the case is in condition for allowance.

Respectfully submitted,

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